Dear Dr Chatfield

RE: BMJ.2018.044852 entitled "The Medical Examiner and patient safety"

Thank you for considering our paper and for the helpful and supportive editorial and reviewer comments. We agree that the comments give us the opportunity to strengthen our manuscript, develop the ideas presented, and allow greater depth to the discussion. We have revised the manuscript to address the comments and hope we have achieved these aims.

The revisions to the manuscript are marked with track changes and our response to each comment is outlined below.

We look forward to your response.

Yours sincerely

Alan Fletcher, Joanne Coster & Steve Goodacre

Editors' Comments:

- In general we found it to be timely and well-written. Could you briefly mention the topical angle of this piece now Jeremy Hunt has made his announcement? Bringing in the topicality would work well

We have rewritten start of the first paragraph so that it briefly describes and cites the Government announcement of the introduction of Medical Examiners.

- your argument would then be that this is a great idea and this is what we know about how to do it from our experience / research.

We have rewritten the rest of the first paragraph so that it highlights the potential value of the initiative and then sets out the purpose of the paper in terms of drawing on our experience and research.

- It is more of an explainer than an analysis. Could you include a little more about the disadvantages/pitfalls of this approach or discuss some barriers to implementing it in practice? What are you trying to say apart from describing what is happening?

We have added a paragraph entitled “What are the potential challenges with implementing the Medical Examiner system?” that describes the disadvantages, pitfalls and barriers to implementation.

- Our editors are not all clinical or UK based and they noted that the paper is confusing unless you know something about how the system works already. There's a lot of assumed knowledge here that you could resolve quite easily by giving some brief explanation about the current system.

We have added a paragraph entitled “What is the current system for examining deaths in England and Wales?” that briefly describes the current system.

- Put the unpublished data in as an appendix - enough information to understand the headline numbers e.g. a table so readers know all the denominators and a little bit of text about how/where it

was collected. This is better practice than referring to unpublished data but not including the data for readers to see.

We have added an appendix consisting of a table that describes the unpublished data from the Medical Examiner pilot site.

- This is very focused on secondary care. How are these roles going to impact on primary care? If they won't, then what is the implication for deaths/patient safety in primary care? A brief consideration of this would be helpful.

We have added a paragraph under "What does a Medical Examiner do" to describe how the planned roll-out of the Medical Examiner is expected to eventually involve primary care. We have also highlighted the potential problems with this in the new paragraph describing the potential problems implementing the Medical Examiner system.

Reviewer: 1

The article (which reached me by email on 28 May) is timely and important. It reports pilot work for a new system of death certification monitoring the Government has for years been planning for in England & Wales and has said will be implemented in 2019. It addresses interesting issues about the relationship between the proposed independent statutory monitoring of death certification and internal health service reviews of patient safety and death preventability. Its authors are well qualified to address the issues. It is properly referenced. Subject to a few small points of detail (as follows) it is convincingly supported.

Thank you for your supportive comments and insightful suggestions. We have amended the paper to ensure that they are addressed.

Page 2, line 17: "United Kingdom" should be "England & Wales". The Medical Examiner scheme has been worked up only for E & W. Scotland has a different one. Northern Ireland has not yet decided what, if anything, to do. In page 3 line 33, the reference should be "in E & W" not "across the UK".

We have amended the text to England and Wales or England, where appropriate.

Page 2, lines 31-33. There is some complexity in the provenance and evolution of the "Medical Examiner" scheme but its attribution to a Shipman Inquiry recommendation is misleading. The Inquiry recommended a different scheme, involving notification of all deaths to the coroner where they would initially be scrutinised by lay staff under medical supervision. The ME scheme had originated in work done by the Department of Health soon after Shipman's conviction and was included for assessment in the terms of reference of the Home Office "Fundamental Review of Death Certification and Investigation" which I chaired and which reported in 2003 a handful of months before the relevant Shipman Inquiry report. The Fundamental Review broadly endorsed and recommended the scheme though suggested a different title. The Shipman Inquiry was critical of the scheme. Since then the scheme has evolved in two significant respects – Medical Examiners would be contracted to local authorities not the NHS and so be more independent, and would be required to consult bereaved families. These changes bring it closer to the Shipman Inquiry proposal. It would be appropriate to say the scheme in its present form "responds to the Shipman Inquiry's analysis of defects in the present arrangements" but not that the Inquiry recommended the scheme.

Thank you for this clarification. We have amended the paragraph "What is the role of the Medical Examiner" accordingly and added a citation for the Home Office report.

Page 3, lines 45-50. The referenced ONS study actually found that 12% of deaths needed change to the ICD classification and a further 10% were less fundamentally wrong. Would it be worth reporting this distinction?

We have amended as suggested.

Page 5, lines 15-20. The proportion of deaths identified in the referenced personal communication that should have been notified to the coroner (153/2668) is 5.7%. The proportion of deaths found to be uncompliant with coroner referral principles in the published study at reference 7 was 8%.

These percentages are reporting slightly different measures. The numerator in the 153/2668 only includes those that should have been reported to the coroner because of clinical governance (patient safety) issues, while numerator in the 7% includes those that were uncompliant in coroner referral principles in other ways. In this section of the paper we are considering clinical governance issues, so are reporting the former rather the latter. We have clarified this in the text. We have also reflected on the appropriate denominator for this percentage and amended it to include all cases considered by the Medical Examiner rather than just those not already referred to the coroner.

On page 6, lines14-21, the issue of the proposed E & W combination of ME and internal hospital reviews is suggested to have the potential of making the mortality review system "the best in the world". This implies that there are no similarly robust and searching schemes elsewhere. This may very well be right but if there were any published literature with international comparisons of death monitoring systems to support the point it would be worth referencing. I am not aware of any myself.

We have undertaken a brief literature search and have not found any international studies that we think would add to the review without detracting from the main focus. We identified several publications describing mortality review systems relating to clinical specialities, most commonly maternity, and publications describing coronial systems in different settings. We also identified publications describing the US version of the Medical Examiner (which as we note below is different from the Medical Examiner role proposed in England and Wales). None of these publications describe a national mortality review system comparable to the one proposed for England and Wales.

A more general point is that the article implies – correctly, I believe – that the pilot projects – and hence the article's evidence base – is confined to E & W hospital deaths. Would it be worth making explicit that the ME scheme is intended also to cover all deaths, whether or not in hospital?

We have addressed this by adding to the paragraphs describing the Medical Examiner role and the potential problems to describe the planned roll-out beyond hospital deaths.

The article is intended for publication in a Journal with wide Anglophone circulation. Would be it sensible to make clear that the "Medical Examiners" proposed for England & Wales are very different in function from North American Medical Examiners? The latter run forensic pathology services for cases referred to them and, generally speaking, do not have the role of monitoring the death certification scheme envisaged for E & W MEs.

We have added this point under "What is a Medical Examiner"

Reviewer: 2

Comments:

A concise and accurate review of the emerging interface between the Medical Examiner function and the developing system of case note review in England and Wales together with the benefits of this alignment particularly in the light of the recent announcement on the progress of the ME system.

Thank you